510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE TEMPLATE

510(k) Number: K032608

Analyte: Primary Calibrator for Osmolality

A. Type of Test: N/A

B. Applicant: Gonotec Gesellschaft Fuer Mess- UND Regeltechnik MBH

C. Proprietary and Established Names: Calibration Solution for Osmomat 010/030/Auto

Regulatory Information:

1. Regulation section: 21 CFR 862.1150

2. Classification: Class II

3. Product Code: JIS

4. Panel: 75

D. Intended Use:

1. Indication(s) for use: The primary calibrator "Calibration Solution for Osmomat 030/Auto" is used to calibrate the Osmometers "Osmomat 030" and "Osmomat Auto" which both are freezing point osmometers for use in clinical chemistry. The Osmolality of the calibrator is equal to the Osmolality of body fluids (isotonic solution), providing that the osmometer will be calibrated correctly for the fluids to be measured for medical purposes.

2. Special condition for use statement(s): none

3. Special instrument Requirements: none

Device Description: IVD device calibration is most commonly performed using calibrators (reference materials) specifically intended to be used as a standard curve or cut-off point for an assay.
A calibrator has an assigned value that is established by the manufacturer by a reference method. Calibrators exist in a variety of matrices such as simulated aqueous, serum, plasma or other types of specimens.
Primary reference calibrators are highly purified chemicals that can be directly weighed or measured to produce a solution of known concentration. Alternatively

they may be more complex biological materials having received a value assignment using reference methodology. They are supplied with a certificate of analysis for each lot (For Example, Standard reference materials (SRMS) from the US National Institute of Standards. (NIST)).

The primary calibrator "Calibration Solution for Osmomat 030/Auto" is used to calibrate the Osmometers "Osmomat 030" and "Osmomat Auto" which both are freezing point osmometers for use in clinical chemistry. The Osmolality of the calibrator is equal to the Osmolality of body fluids (isotonic solution), providing that the osmometer will be calibrated correctly for the fluids to be measured for medical purposes.

Substantial Equivalence Information:

4. Predicate device name(s): King Sodium/Potassium Standard modified.

5. Predicate K number(s): K931834

3. Comparison with predicate: The Predicate device is a sodium/potassium standard to calibrate ion-selective electrodes. The calibrator consists of an aqueous solution of salts in water. The difference in intended use is not relevant for the safety and effectiveness of the calibrator as the measuring principles in both calibrators are physical not chemical.
The respective calibrators do not react as chemicals in the measurement itself, but their physical properties are measured without changing their chemical composition.
In the case of the Osmomat 010/030/auto, the liquid calibrator is frozen under controlled conditions. The exact temperature needed to induce freezing of the sample is measured. This temperature is a measure for the exact number of molecules of any diluted substances in the aqueous sample.

E. Standard/Guidance Document Referenced (if applicable) The quality of sodium chloride and sevenfold distilled water as sole ingredients of the calibrator itself are checked and controlled under standards accepted by the U.S. Pharmacopeia. Both sodium chloride and water are regulated by European Pharmacopeia. The sodium chloride used is under control of the U.S. Pharmacopeia as well.

F. Test Principle: N/A

Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:* N/A

    b. *Linearity/assay reportable range:* N/A

c. Traceability (controls, calibrators, or method): A certificate of analysis is commercially available confirming the quantity by weight of sodium and chloride in each calibrator lot.

d. Detection limit (functional sensitivity: N/A

e. Analytical specificity: N/A

f. Assay cut-off: N/A

2. Comparison studies:
   a. Method comparison with predicate device: N/A

   b. Matrix comparison: N/A

3. Clinical studies:
   a. Clinical sensitivity: N/A

   b. Clinical specificity: N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

G. Conclusion: Based upon the information provided, I recommend that the Gonotec Gesellschaft – Calibrator for the Osmomat 010/030 and Osmomat Auto be found substantially equivalent with the predicate devices as defined in 21 CFR 862.1150.